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RECORD OF ORAL HEARING
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARC DOLATKHANI and ALAIN DEFFIEUX

Appeal 2008-0526
Application 09/486,065
Technology Center 3700

Oral Hearing Held: August 13, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANT:

Andrew J. Patch, Esquire
YOUNG & THOMPSON
745 South 23rd Street
Second Floor
Arlington, Virginia 22202

PROCEEDINGS

MS. BEAN: Good morning. Calendar Number 11, Mr. Patch.

JUDGE ADAMS: Thanks, Lisa. Good morning, Mr. Patch.

MR. PATCH: Good morning, Your Honor.

JUDGE ADAMS: Been a long time since I've seen you.

MR. PATCH: The privilege is mine.

JUDGE ADAMS: As you know, you have -- we're familiar with your issues. You have 20 minutes and you can begin when you're ready.

MR. PATCH: Thank you. May it please the Board, there are six prior art rejections that are presented for review by this Appeal. Only two of those apply to the sole independent Claim that's pending on appeal, so that if Your Honors were to be of the same view as the Appellant, that the anticipation rejections of that independent Claim need to be reversed, then it would not necessarily be necessary to reach the other four prior art rejections. I'll address each of them, but with the time and emphasis that I think is appropriate to each. And, as always I welcome any questions from the Board as, as I go through.

JUDGE ADAMS: Okay, if you wouldn't mind then, if you could spend a little bit of time with this Claim 68, and it seems that there is a little bit of controversy on the record as to whether this is a product by process claim wherein the limitations with regard to the functional groups and such are not given much weight versus those are, those are important limitations to the claim that define the product.

MR. PATCH: Right. I'd be happy to do that, Your Honor. It, it's not a process -- product by process claim, and if the limitations pertaining to the functional groups can be properly disregarded, then I, I think we've had it as far as the, the strength of our appeal because all, all that the claim recites

other than the, the nature of the functional groups is an intraocular implant with a harder region and a softer region which of course is known.

We were in this invention trying to remedy some of the disadvantages of the prior art in terms of how to house such an implant with those two distinct types of regions and have them be better integrated than they had been in the prior art of which the inventors were aware when the application was filed.

But to go back to your specific question, what Claim 68 says is that we have a flexible material and a relatively rigid material. But it also says that the flexible material comprises functional groups anchored on the material of the lens which allow copolymerization with a mixture of monomers or polymers.

I believe that is clearly structural language that characterizes the product itself, and it may speak to some extent to the manner in which the rigid material is formed, namely, by copolymerization with a mixture of monomers and/or polymers, but it doesn't, in our view, cause the recitation regarding the functional groups to be nonstructural in nature.

JUDGE ADAMS: So you say you see this different than, for example, we claim protein X wherein protein X is produced in a bacterium.

MR. PATCH: Sure, I think that's -- that would be a fairly standard example of product by process where the, the manner in which the product is made doesn't bear on the patentability of the product, at least not in the direct prosecution in the patent offices. Manner --

JUDGE ADAMS: So, why doesn't this, why doesn't this language wherein said flexible material comprises functional groups get to how this product's lens is made?

MR. PATCH: Because functional groups are a structure. Functional groups are chemical moieties that have some function or have some characteristic. And here we say not only that there are functional groups, which is the first element of structure, but also that these functional groups are anchored on the material of the lens, which is a second element of structure. And further, that the nature of these functional groups is such that they allow copolymerization with a mixture of monomers and/or polymers. So there are three distinct aspects of structure, we believe, in the recitation pertaining to the functional groups.

JUDGE FREDMAN: In the recitation, what I wonder is is this lens -- because you say a flexible material and a rigid material, and then there's this thereby cause at the end resulting in a structural modification which selectively increases the rigidity. So is it that you start with a flexible material that has functional groups anchored on it that you copolymerize and you then create the rigid material around the edge?

MR. PATCH: That, that's right, Your Honor. To take it back one more step, we start with a flexible material. The entire lens is made of a flexible material. It is then treated so that the functional groups are added to it and anchored to the material of the lens, and then those functional groups are copolymerized to create the rigid regions, but the flexible material remains throughout the body of the lens.

JUDGE FREDMAN: So the argument that I would make --

or not that I would take this position, mind you, but is that we have a starting material that's flexible, we have a final material that is flexible with rigid around it, we certainly have an intermediate material in which there are functional groups either placed on the, on the flexible ends or they were there originally. It sort of doesn't matter, but it seems like the functional groups represented intermediate between the initial product and the final product.

MR. PATCH: Well, I think that the functional groups may be modified en route to reaching the final product, but I think that they remain present in the material, and that the recitation is accurate with respect to the product.

JUDGE FREDMAN: But see, so that the question of allocation of burden becomes a significant one here, because if I am a person and we take the situation of Judge Adams with the protein produced by a bacteria X, the issue is always if I have another protein produced by a different bacteria it may or may not be the same effect, right, alternately carcasselated (phonetic sp.) or something?

MR. PATCH: Sure.

JUDGE FREDMAN: But the Examiner will often take the argument, you know, *In re Best* and say well presumably they're the same. You know, the burden that I'm shifting to you to show that they're different.

MR. PATCH: Right.

JUDGE FREDMAN: In the same question here the Examiner ends up in, in both of these references I think, Benz maybe a little more questionably in fairness. You know, Osamu pretty clearly though, but in Benz

questionably. We'll take Benz because I think it's a little more questionable. He arguably ends up with a rigid material in the haptic layer on the outside and this, you know, softer layer on the inside. He doesn't -- we don't really know -- how Benz is getting it the reference is a little bit unclear to me, although the -- so if we can't tell, is not then the burden shifted to you to show that they're really different? Because he may or may not have functional groups and the Examiner simply cannot tell.

MR. PATCH: Well, I mean, I, I agree with what you said as a characterization of the proper role of the respective burdens between the Office and the Applicant in the case of the product by process, but I return to the fact that I don't view Claim 68 as being a product by process claim. It has, as we said in our Briefs, three structural features which are the flexible material, the rigid material, and these functional groups. And as I was just saying in response to Judge Adams' question, the functional groups recitation, in turn, has three distinct structural features --

JUDGE FREDMAN: So you're claiming the intermediate? That's what you're saying? We're viewing this as the intermediate with the functional groups on it, or should we be reading this as the final product with the rigid material?

MR. PATCH: It's both. I mean, in the sense that we have a recitation in the claim of a relatively rigid material that's there.

JUDGE FREDMAN: Well, right.

MR. PATCH: And, and we also have a recitation in the claim of functional groups that are anchored on to the flexible material, that too is there. Now the point that I was trying to make earlier is that the functional

groups, once they're copolymerized with the final ingredient, if you will, to form the rigid material, they may be altered in their nature to some extent, but they remain the functional groups that are recited in the claim. So we say that all three of those things are there.

With respect to the question of how is this distinct from the prior art without reading it as product by process, I think you can read it almost any way you please, and it's distinct from the prior art in any event, which is to say the prior art doesn't have or does not disclose -- and I should qualify my remarks to the context of the applied grounds of rejection. The Osamu and Benz references do not disclose a flexible material in which you have relatively rigid regions and which you have functional groups that are anchored on the flexible material which permit this copolymerization with the mixture or monomers and polymers.

JUDGE ADAMS: If I can back you up just a little bit?

MR. PATCH: Yeah.

JUDGE ADAMS: We have these two options. At this point, we have two options on the table. Read this claim as a product by process or don't read it as a product by process and actually read these functional groups as positive limitations in the claim define this "structure of the lens".

On the one hand we're -- if we were to read it as a product by process you would concede that the prior art anticipates this lens. Both Benz and Osamu teach a lens that's rigid on -- have both rigid material and flexible material. Is that right? I think you started off with that statement when you walked in.

MR. PATCH: Not quite right, Your Honor. I understand the, the point you're trying to make. I don't, I don't concede that if this claim is read in any way as being product by process that it is necessarily anticipated. The point I was trying to make is that if the Board feels that it is entitled to entirely disregard all of the language pertaining to the functional groups, then what precedes it is simply a recitation of a lens with a rigid region and a flexible material --

JUDGE ADAMS: So --

MR. PATCH: -- and that much is admittedly known.

JUDGE ADAMS: Okay, so isn't that a concession then that Osama or -- yeah, Osamu and Benz anticipate that claim? You say that intraocular lens comprising a flexible material and at least one rigid -- relatively rigid material is known in the art, right?

JUDGE FREDMAN: Assuming that you're going at that route.

JUDGE ADAMS: Right.

MR. PATCH: Oh, and that's, that much is--

JUDGE ADAMS: That would be the product of process.

MR. PATCH: That much is discussed in the background of our Specification.

JUDGE ADAMS: So that would be a concession that Osamu and Benz then anticipate your claim, if we read just that limitation as product by process?

MR. PATCH: Well, let me --

JUDGE FREDMAN: Reading out the where of flexible material because we say that that's part of the process of making.

MR. PATCH: Let me put Claim 68 before me so that I will make sure to make a fully informed concession.

JUDGE ADAMS: I hope so.

MR. PATCH: I think that if you believe that Claim 68 can properly be read to simply stop at Line 2, that is if the --

JUDGE ADAMS: Right before the wherein clause?

MR. PATCH: Exactly.

JUDGE ADAMS: For a period at the where at?

MR. PATCH: Exactly. If you can stop there after rigid material, then that would, that would read on Osamu. We don't believe it would read on Benz.

JUDGE ADAMS: Okay.

MR. PATCH: It would also read on a number of the prior art references that are discussed in the background of our Specification.

JUDGE ADAMS: So --

MR. PATCH: We don't claim to have invented the concept of combining a rigid material --

JUDGE ADAMS: I understand.

MR. PATCH: -- and a flexible material on a lens rather --

JUDGE ADAMS: I understand where you're going.

MR. PATCH: Yeah.

JUDGE ADAMS: So my next question would be you're asking us to in fact read this claim as a Jepson claim. So it's an intraocular lens that's comprising of flexible material and at least one relatively rigid material

wherein the improvement comprises the flexible material for comprising functional groups yada, yada, yada.

MR. PATCH: Well, it's not a Jepson Claim, but I don't think it would be an inaccurate characterization of the record before you to treat it as a Jepson Claim because it is acknowledged in the background of our Specification that lenses with flexible material and rigid material are known. What we've done is to make one with a different structure.

JUDGE ADAMS: Right. Well, your improvement is adding these functional groups anchored on. Is that correct?

MR. PATCH: That's, that's, that's one of a number of improvements. It's the one that we ended up claiming here. The case has been pending for a while, and the claims as filed were significantly broader than the independent Claim 68 which is before you. And when you consult the Specification, say, in the vicinity of pages 6 and 7, we recite a number of different approaches, not all of which are covered by this independent Claim 68.

So one of those, for example, is essentially cross-linking the flexible material to harden it, and that's not what's claimed in Claim 68. Claim 68 is the concept of anchoring a functional group to the flexible material --

JUDGE ADAMS: Well, I think we're getting a little off your claim. My, my point was your claimed improvement would be anchoring these functional groups to this, to this material, the lens, right? You might have a whole variety of different improvements disclosed in your Spec., but what you're claiming would be the improvement listed in the after the wherein clause, right?

MR. PATCH: I don't think it's probably accurate to parse the claim in exactly that way, the reason being, Your Honor, that when we recite a rigid material in line 2 prior to the wherein clause that is conceptually related to the existence of the functional groups that are anchored on the lens material because the nature of these functional groups is that they allow the copolymerization in order to create the rigid material.

So I would retreat from my concession to, to that extent in that I think that that there is some, some linkage in the recitations before and after the, the wherein clause, at least in that respect.

JUDGE GREEN: Can we talk about the Osamu reference, because I think your time is getting short and I --

MR. PATCH: Sure.

JUDGE GREEN: -- think that that's, that's a concern?

MR. PATCH: Yeah.

JUDGE ADAMS: In that, in that regard, if we could just jump right ahead, we're going to assume for the moment that all these limitations in your claim, including after the wherein clause, are positive limitations on the claim, and I'm going to direct your attention to the teaching in Osamu that would say you take a lens compound, you attach functional groups to it, then you modify these functional groups to create a rigid part of that lens. And that would be at sections -- or at pages 4 and 5 of the Osamu reference.

MR. PATCH: Okay, Your Honor, that's fine. And I think that is probably the most efficient use of the remaining time.

JUDGE ADAMS: Yes.

MR. PATCH: And, and I appreciate your direction in that respect. I would note that apparently the part that you're referring to, which is Paragraphs 6 --

JUDGE ADAMS: Six.

MR. PATCH: -- and 7 --

JUDGE ADAMS: Correct.

MR. PATCH: -- of the Osamu translation, were not relied upon by the Examiner in the rejection in making the anticipation rejection. He relied solely upon the parts of the reference that refer to taking a material and softening the central region by treating it with alcohol rather than any type of hardening treatment of the haptic regions of an implant, which is, of course, what the invention is related to. I wanted to note that as a point of procedure protocol that we are discussing a part of the reference not relied upon in the rejection before you.

JUDGE ADAMS: Well, you -- did you have the reference available to you?

MR. PATCH: Of course.

JUDGE ADAMS: And you read it?

MR. PATCH: I did.

JUDGE ADAMS: So you were on notice, right?

MR. PATCH: Well, notice, whether or not it constitutes notice, I came prepare to discuss it.

JUDGE ADAMS: All right.

MR. PATCH: And I did just want to make --

JUDGE ADAMS: All right.

MR. PATCH: -- that point for the record, that we're, we're diverging from the rejection as made by the Examiner, but I think it's appropriate that we talk about it.

JUDGE ADAMS: Absolutely.

MR. PATCH: Okay. So in paragraph 6 Osamu does mention that rather than softening the central part of the material you can instead harden the peripheral parts of the material. And there is indeed reference to functional groups; that term is used. The remainder of the disclosure and all the specific disclosure in the examples pertains to the softening of the central region.

In paragraph 6 and 7, you have this reference, and, in particular it's paragraph 7, where there's a reference to a method of introducing the functional groups which may make a polymer harden. It's hard to know what Osamu is talking about there, but it certainly sounds interesting with our Claim 68 before you. But it's not an anticipatory disclosure of what is recited in our Claim 68.

I go back to the point I was starting to make earlier, that our Specification at pages 6 and 7 discusses that there's a variety of ways in which the inventor has contemplated hardening creating these rigid regions on the lens, not all of which are claimed. One of those, for example, is cross-linking in which they refer to the use of a polyfunctional material, and cross-linking I think connotes polyfunctionality in that the cross-linking agent has presumably two connection points in which to bind together a chain.

If I had to guess what Osamu was talking about in paragraph 7, it sounds like cross-linking because they're speaking of hardening a polymer material with functional groups. We're not claiming cross-linking in our Claim 68. We're, we're, we're speaking of instead -- we're not claiming it explicitly or implicitly --

JUDGE ADAMS: Correct.

MR. PATCH: -- because we're speaking instead of reactive functional groups that are anchored to the lens material that permit the copolymerization. And so, rather, what we're talking about in Claim 68 is the technique of forming an additional polymer material outside of the lens material, and there's reference to that, for example, at Page 6, Lines 13 to 20 of our Specification, page 7, lines 20 to 29, page 8, lines 2 to 17.

JUDGE FREDMAN: I suppose if you bound a cross-link to a flexible material you'd have an anchored functional group.

MR. PATCH: I'm sorry, Your Honor?

JUDGE FREDMAN: I suppose if you took a cross-link and bound it to a flexible material, you'd have an anchored functional group.

MR. PATCH: I think -- my conception of a cross-link anchor is that you would have a compound which is anchored at the location, anchored to the lens material at the location of each of its functional groups, and so not available for copolymerization with a polymer outside the lens.

JUDGE ADAMS: Okay. Well, I think we're getting a little off, off tangent here because what we're talking about, this copolymer, is, is this -- this language we're talking about isn't in the claim, right? This, this subject matter. What I'd like to really -- because we're really running into time, I'd

really like to focus your attention to the line right above paragraph 7 and assume where it talks about this method (d). And it says a method where after forming a lens base from a material consisting of a reactive single mass polymer only the optical part is processed to soften or alternatively, emphasis on the alternative, only the peripheral part is processed to harden.

Then dropping down in paragraph 7, to the methods by which Osamu discloses how you would harden this peripheral part, he, he mentions, as you read, that it would include introducing functional groups which may make the polymer harden. So tell me exactly why it's your position that that doesn't read as an anticipatory reference on your Claim 68.

MR. PATCH: Because, Your Honor, there are a whole host of ways in which functional groups can be utilized --

JUDGE ADAMS: And, your claim includes them all?

MR. PATCH: I, I disagree with that, Your Honor.

JUDGE ADAMS: Okay, tell me why.

MR. PATCH: We recite that we have functional groups which are anchored to the lens material and which allow copolymerization with a mixture of monomers and/or polymers and, and that is a specific type of functional group, one that is not disclosed by the passages of Osamu that we have referred to. Nor, I would say --

JUDGE ADAMS: So, your argument --

MR. PATCH: -- even suggested by those passages.

JUDGE ADAMS: So your argument would be while Osamu generically suggests what you're claiming, he doesn't particularly point out

this attachment of functional groups to the lens wherein monomers or polymers are copolymerized?

MR. PATCH: I wouldn't, I wouldn't agree with that characterization of Osamu generically suggesting what we are claiming. Rather, I would say that Osamu makes reference to functional groups, the utilization of some sort of unspecified functional groups in order to harden a portion of the lens. He then moves away from that to the balance of the disclosure to discuss what he is more interested in, which is softening the central part of the lens. He doesn't describe any particular techniques, and therefore, especially in light of our own disclosure at pages 6 and 7 which describe that there's quite a variety of ways in which the inventors contemplated doing this, we feel that there is no disclosure or suggestion of the particular way that we ended up claiming in Claim 68. It's also, I think, reinforced if we want to focus on this part of Osamu. And, I agree with Your Honor that it is the most pertinent part of the reference, even though, again, it wasn't what the Examiner had relied upon.

I would focus on the phrase that refers to hardening the polymer. We're not really doing that in what we recited in Claim 68. It's not that we're hardening the flexible material. We're forming another copolymer above it which serves to rigidify that region of the lens, but we retain flexible material throughout the lens.

JUDGE ADAMS: Okay, and it would be your position with regard to the 103 Rejection that based on this that the Secondary Reference doesn't make up for these – this deficiency in Osamu?

MR. PATCH: Well, I think with respect to certain of these 103 Rejections it's, it --

JUDGE ADAMS: Well, I believe there's only one over or in combination with Osamu, Osamu. Is that correct?

MR. PATCH: I'm, I'm sorry, Your Honor?

JUDGE ADAMS: All the rest are -- there's only one 103 Rejection that involves Osamu, Osama, the O reference.

MR. PATCH: That's correct, Your Honor.

JUDGE ADAMS: Okay. And with regard to the Benz reference, the position would be that the Benz doesn't even say or that he's interested in making a flexible lens that has a flexible and a rigid part. He doesn't even get you to that, let alone the remainder of this, of this Claim 68. Is that right?

MR. PATCH: That is a fair characterization --

JUDGE ADAMS: And that a --

MR. PATCH: -- of our position with respect to Benz.

JUDGE ADAMS: -- that a various 103 rejections based on Benz don't make up for that deficiency. Is that right?

MR. PATCH: I, I, I agree with that, Your Honor, with respect to the 103 rejection involving Osamu and Vanderbilt. I would point to our Claim 24 and the recitation there of a copolymer of what we've abbreviated as MMA and HMA, and I really do not find in either Osamu or Vanderbilt a description of that copolymer.

JUDGE ADAMS: Anything else you'd like to emphasize for us?

MR. PATCH: Well, with the, the last of the six rejections which involves Benz and Wang, again the remarks that Your Honor made in summarizing our position as to Benz applies also for those dependent claims. But, with Wang we think it's fairly clear from the explicit disclosure at column 2, lines 54 to 57 of Wang that his further treatment of the lens material involves no direct bonds to any reactive groups located on the surface of the polymer substrate is exactly the opposite of what we're calling for in our Claim 68.

And this is therefore in Wang more in the nature of an interpenetrated polymer as opposed to a surface linked polymer. And, and, and again in our Specification we mention interpenetrated polymer networks at page 6, line 13-20, another example of something that we're not claiming in Claim 68.

JUDGE ADAMS: Okay. Any questions? Questions? All right, thank you for your time.

MR. PATCH: Thank you, Your Honor.

(Whereupon, the hearing concluded at 9:28 a.m. on August 13, 2008.)